

tomy conditions of purchase and use. (5) In that the carton containing the set did not bear an accurate statement of the quantity of contents.

On June 24 and September 25, 1941, no claimant having appeared, judgments were entered ordering that the product be destroyed.

434. Misbranding of Happy Day Headache Powders. U. S. v. 21½ Gross Packages of Happy Day Headache Powders. Default decree of condemnation and destruction. (F. D. C. No. 4008. Sample No. 50903-E.)

This product would be dangerous to health when used according to directions, its labeling failed to bear adequate directions for use and warning statements, and in addition it bore false and misleading therapeutic claims.

On or about March 21, 1941, the United States attorney for the Western District of Virginia filed a libel against 21½ gross packages of Happy Day Headache Powders at Roanoke, Va., alleging that the article had been shipped from Winston-Salem, N. C., in part in the personally owned automobile of Max Caplan, owner of the Capital Drug Co., Roanoke, Va., on or about September 16, 1940, and in part by the Sessions Specialty Co. on or about November 8, 1940; and charging that it was misbranded. It was labeled in part: "Happy Day Headache Powders * * * Manufactured by Gulf Laboratories Inc. Lafayette Louisiana."

Analyses of samples of the article showed that it consisted essentially of acetanilid (2½ grains per powder), aspirin, caffeine, phenolphthalein, and milk sugar.

The article was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, (envelope containing powder) "Directions Take one powder dry on the tongue followed with water, or mixed with a little water. One powder usually gives the desired results. If necessary, another powder may be taken in 30 minutes. Women will find this especially beneficial during painful menstrual periods"; (circular) "Take one powder dry on the tongue, followed by a swallow of water, or mix well with small quantity of water and take. Repeat in 20 minutes if necessary. One powder usually gives relief. Children over 6 years: ¼ to ½ of one powder. * * * One powder well mixed in a little water at the first sign of cold or fever and one two hours later. One powder at night just before retiring is recommended. Children over six years: ½ powder mixed in water 3 times daily according to age. * * * One powder dissolved in water every 2 or 3 hours as required." (2) In that the labeling failed to bear adequate directions for use. (3) In that the labeling did not bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users. (4) In that statements in the labeling representing that it would be efficacious for the relief of discomfort arising from head colds, hay fever, and nervousness; that it would reduce fever, insuring speedy relief; that it would be efficacious for the relief of pains caused by menstrual disturbances, tonsillitis, headache caused by sinus trouble, rheumatism, influenza, and throat irritations, were false and misleading since it would not be efficacious for such purposes. (5) In that the label did not bear the common or usual names of the active ingredients. (6) In that the label did not bear an accurate statement of the quantity of contents.

On July 15, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

435. Misbranding of Suppletive Formula Number 1, Supportive Formula S. G. M. a, and Formula No. 1. U. S. v. 326 Ampuls of Suppletive Formula Number 1, 88 Ampuls of Supportive Formula S. G. M. a, and 2 Bottles of Formula No. 1. Default decrees of condemnation and destruction. (F. D. C. Nos. 3318, 3548, 3549. Sample Nos. 30843-E, 31909-E, 31912-E.)

Examination of Suppletive Formula Number 1 disclosed that it contained emetine hydrochloride. This product would be dangerous to health when used in the dosage suggested in the labeling. Its label and that of Formula No. 1 failed to bear such warnings as might be necessary for the protection of users. All three products failed to bear adequate directions for use and to name the active ingredients present.

On November 16 and December 20, 1940, the United States attorney for the Northern District of Illinois filed libels against the above-named products at